K063554

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JAN 12 2007

510(k) SUMMARY

Contact: Dr. Süs

Date prepared: November 24, 2006

Trade or proprietary name: Meron Plus

Classification name: Cement, Dental, (872.3275)

Predicate device: Fuji Duet (Fuji Plus), K946100

Device description: Meron Plus is a resin reinforced chemically curing glass ionomer cement for permanent cementation. It is delivered in bottles for mixing by the dentist as well as in capsules (so called application capsules "AC") for the better handling and ease of use. The device is characterized by high adhesion to tooth structure.

Intended use: Meron Plus is intended for permanent cementation of porcelain-fused-to metal crowns, bridges on hard dental tissue and cores rebuilt with amalgam, composite or glass ionomer cements. Meron Plus is further intended for the permanent cementation of metal inlays, onlays, crowns and bridges, posts, crowns manufactured from alumina-only or zirkonia-only cores and orthodontic appliances

Technological characteristics: All of the components of Meron Plus are found in the legally marketed devices K946100, K062292, K040769, K052820.

The prior use of all of the components Meron Plus in legally marketed devices support our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

We believe that the prior use of the components of Meron Plus in legally marketed devices and the performance data and results provided support the safety and effectiveness of Meron Plus for the intended use.

VOCO GmbH, November 24, 2006

Dr. Michael Süs
Mgr. for regulatory affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Michael Süs
Manager for Regulatory Affairs
VOCO GmbH
Anton-Flettner-Strasse 1-3
27472 Cuxhaven
GERMANY

JAN 12 2007

Re: K063554
Trade/Device Name: Meron Plus
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: November 24, 2006
Received: November 27, 2006

Dear Dr. Süs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

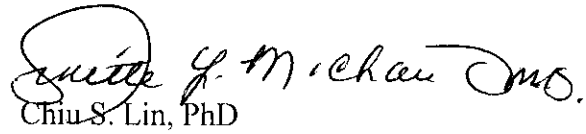
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K063554

Device Name: **Meron Plus** ____

Indications for Use:

Meron Plus is intended for permanent cementation of porcelain-fused-to metal crowns, bridges on hard dental tissue and cores rebuilt with amalgam, composite or glass ionomer cements. Meron Plus is further intended for the permanent cementation of metal inlays, onlays, crowns and bridges, posts, crowns manufactured from alumina-only or zirkonia-only cores and orthodontic appliances.

Prescription Use __X___ OR **Over-The-Counter Use _____**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(POD)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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